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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/068,377	05/08/1998	LAURENCE A. LASKY	P1066P2	2255

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EXAMINER	
RAWLINGS, STEPHEN L	
ART UNIT	PAPER NUMBER
1642	33

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/068,377	Applicant(s) LASKY ET AL.	
	Examiner Stephen L. Rawlings, Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2002 and 07 May 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 16-21* is/are pending in the application.

4a) Of the above claim(s) *1-14 and 19-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-18 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-14 and 16-21* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. The amendment filed on June 7, 2002 in Paper No. 32 is acknowledged and has been entered.

2. The amendment filed on February 21, 2002 in Paper No. 29 is acknowledged and has been entered. Claims 15 and 23 have been canceled. Claims 16-18 have been amended. Claim 24 has been added.

3. Claims 1-14 and 16-21 are pending in the application. Claims 1-14 and 19-21 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim. Applicants timely traversed the restriction (election) requirement in Paper No. 12.

4. Claims 16-18 and 24 are currently under prosecution.

Grounds of Claim Rejections/Objections Withdrawn and Reply to Applicants' Remarks

5. Unless specifically reiterated below, the grounds of rejection or objection that were set forth in the previous Office Action mailed November 18, 2001 (Paper No. 18) have been rendered moot by Applicants' amendment or withdrawn upon consideration of Applicants' grounds of traversal.

Nevertheless, to promote the clarity of the record, some of Applicants remarks merit further reply. With regard to the grounds of rejection of claims 15-18 under 35 USC § 103(a) as being unpatentable over GenBank Accession no. MMU87814 (Lasky, submitted January 29, 1997) in view of Ackerman (*Human Cell* **1**: 46-53, 1988), Applicants traversed these grounds of rejection arguing, "[t]he Lasky reference cited by the Examiner describes the inventors' own work and is not a publication by 'others' as required by 35 U.S.C. § 102(a)" (Paper No. 29; page 3, paragraph 2). Therefore, Applicants asserted that the "Lasky reference" is not available as prior art.

In reply to these remarks, L. Lasky is a co-applicant, not the inventive entity. Accordingly, contrary to Applicants' remarks, it is proper to regard the L. Lasky as someone other than the inventive entity, or someone other than the applicant for a patent based upon this application. Furthermore, it is noted that 35 USC § 102(a) reads as follows:

> A person shall be entitled to a patent unless -
> (a) **the invention was known or used by others in this country**, or patented or described in a printed publication in this or a foreign country, **before the invention thereof by the applicant for a patent** (emphasis added).

The reference cited as the basis of the rejection provides evidence that one of the co-applicants, namely L. Lasky knew of a nucleic acid molecule encoding the polypeptide to which the claimed antibodies must bind before the invention thereof by the applicant for a patent based upon this application. In addition, it is evident that L. Lasky had to have used the nucleic acid molecule on or before the date of the submission to the database and before the invention thereof by the applicant, because otherwise L. Lasky could not have determined the polynucleotide sequence of the nucleic acid molecule. On the other hand, the reference provides no factual evidence that the applicant for a patent, namely the inventive entity of Laurence A. Lasky and Donald J. Dowbenko, knew of or used the invention on or before the date that L. Lasky submitted the polynucleotide sequence of the nucleic acid molecule to the database, but since the reference provides evidence that one of the co-applicants, and not the inventive entity or applicant for a patent, knew of and used the nucleic acid molecule encoding the polypeptide to which the claimed antibodies bind, it would appear that the reference should be regarded as prior art under 35 USC § 102(a). Given the benefit of the knowledge that it is evident that L. Lasky had at the time the submission to the database, it would have been obvious to one of ordinary skill in the art to produce an antibody that would bind specifically to the polypeptide encoded by the nucleic acid molecule of L. Lasky for the reasons set forth in the grounds of rejection.

Nevertheless, despite the fact that the statute reads, "unless – (a) the invention was know or used by others in this country [...] before the invention thereof by the applicant for a patent", the Office has apparently taken the position that the evident knowledge of L. Lasky must be regarded as having had a reasonable probability of dissemination and have been publicly

accessible before the invention thereof by applicants for a patent, i.e., before the filing date of this application, to be regarded as prior art. See MPEP § 2128. Accordingly, although evident that L. Lasky knew of and used the nucleic acid molecule to which the claimed antibodies bind before the application was filed, this knowledge would not have had a reasonable probability of dissemination to the public before the filing date of the application. Therefore, the grounds of rejection of claims 15-18 under 35 USC § 103(a) have been withdrawn.

Grounds of Claim Rejections Maintained and Reply to Applicants Remarks

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 16-18 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Database GenBank Accession No. AI322422 (Marra, et al, 1996) in view of Ackerman (*Human Cell* **1**: 46-53, 1988) for the reasons set forth in the previous Office Actions (Paper Nos. 14, 19, and 28).

In reply to the previous Office Action mailed November 21, 2001 (Paper No. 28), Applicants have traversed this ground of rejection under 35 USC § 103(a) arguing the reference fails to anticipate the claimed invention because the "Marra does not teach or suggest the full length PSTPIP of SEQ ID NO: 1, or even a fragment thereof" (Paper No. 32; page 2, paragraph 3). Applicants have also asserted that the primary reference fails to teach or suggest antibodies directed against a protein encoded by the nucleic acid molecule and furthermore that neither of the references provide a suggestion or motivation to make such an antibody.

In reply to Applicants' remarks, the claims are drawn to an antibody that binds the polypeptide of SEQ ID NO: 1. The primary reference teaches the polynucleotide sequence of a messenger RNA molecule, which would be reasonably expected to encode a polypeptide. As a 507 nucleotide region of the polynucleotide sequence of the prior art is 99% similar to the polynucleotide sequence set forth in SEQ ID NO: 2, it would be reasonable to expect that the

amino acid sequence of the protein encoded by the polynucleotide sequence of the prior art would be very similar to the amino acid sequence set forth in SEQ ID NO: 1, which is encoded by the polynucleotide sequence of SEQ ID NO: 2. In fact, the results of a sequence search using SEQ ID NO: 1 as a query indicates that the polynucleotide sequence of the prior art could encode an amino acid sequence that is 98.2% identical, or 98.8% similar to the amino acid sequence set forth in SEQ ID NO: 1. Therefore, the predicted amino acid sequence of the polypeptide encoded by the nucleic acid molecule of the prior art is evidently very similar to the amino acid sequence of PSTPIP, so much so that the sequence of the prior art is annotated as such. For these reasons, it is reasonable to expect that an antibody produced by immunizing an animal with the polypeptide encoded by the nucleic acid molecule of the prior art would bind the polypeptide of SEQ ID NO: 1. Accordingly, the antibody that would have been obvious to one of ordinary skill in the art to produce, at the time the invention was made, is deemed the same as the antibody of the claims, absent a showing of an unobvious difference. The Office, however, does not have the facilities for examining and comparing Applicants' product with the product of the prior art in order to establish that the product that would have been obvious to produce given benefit of the prior art does not possess the same material, structural, and functional characteristics of the claimed product or would not function identically as the claimed antibody. In the absence of evidence to the contrary, the burden is upon the Applicants to prove that the claimed antibody is functionally different than those rendered obvious to make and use by the prior art and to establish patentable differences. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ 2d 1922 1923 (PTO Board of Patent Appeals and Interferences).

Moreover, although Applicants have correctly noted that the primary reference does not teach the polynucleotide sequence encoding the polypeptide of SEQ ID NO: 2, the binding specificity of an antibody is an inherent property of the antibody. In other words, despite the evident differences in the amino acid sequences of PSTPIP and the polypeptide encoded by the nucleic acid molecule of the prior art, it is not necessary that the polypeptide encoded by the nucleic acid molecule of the prior art be identical to PSTPIP to produce an antibody that binds to PSTPIP. An antibody that binds a common epitope will bind both proteins. In view of the predicted similarity of the proteins, one of skill in the art would have had a reasonable

expectation of successfully producing the claimed invention by immunizing an animal with the polypeptide encoded by the nucleic acid molecule of the prior art.

Furthermore, as stated in the previous Office Actions, it would have been obvious to one of ordinary to skill in the art to produce an antibody that binds the polypeptide encoded by the nucleic acid molecule of the prior art. The methodology required to do so was both routine and conventional at the time the invention was made. The Board of Patent Appeals and Interferences has taken the position that once an antigen has been isolated, the manufacture of monoclonal antibodies against the antigen would be obvious in the absence of some suggestion to the contrary. One would have been motivated to manufacture an antibody that binds the polypeptide encoded by the nucleic acid molecule of the prior art by immunizing an animal with a polypeptide comprising at least a portion of the predicted amino acid sequence encoded by the nucleic acid molecule, because the utility of such antibodies was much appreciated in the art at the time the invention was made. Nonetheless, the disclosure by Ackerman would have provided ample suggestion and motivation to one of ordinary skill in the art to do so.

Accordingly, Applicants' arguments have been carefully considered but have not been found persuasive. Therefore, the rejection of claims 16-18 and 24 under 35 USC § 103(a) for the reasons set forth in the previous Office Action mailed November 21, 2001 (Paper No. 28) is maintained.

New Grounds of Claim Rejections

Claim Rejections – 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 16-18 and 24 are rejected under 35 USC § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, has possession of the claimed invention.

There appears to be inadequate antecedent basis for recitation of the limitation "at a site not including a phosphorylated tyrosine" in the specification. Such a limitation recited in the present claims, which if not supported by disclosure in the specification, would introduce new concepts and violate the written description requirement of 35 USC § 112, first paragraph.

Moreover, because claim 24 recites "[a]n antibody that binds the [...] polypeptide of SEQ ID NO: 1 at a site not including a phosphorylated tyrosine", it appears that the claim is directed to a subgenus of antibodies, which was not described by the original disclosure of the genus of antibodies that bind a PSTPIP polypeptide comprising the amino acid sequence of SEQ ID NO: 1. Applicants are reminded that it cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See *In re Smith*, 173 USPQ 679, 683 (CCPA 1972).

Furthermore, for this reason, it appears that the phrase "at a site not including a phosphorylated tyrosine" is a negative limitation since it is intended to exclude anti-phosphotyrosine antibodies that bind the polypeptide of SEQ ID NO: 1. Once again, adding the expressed exclusion of certain elements implies permissible inclusion of all other elements not so expressly excluded. This clearly illustrates that such negative limitations, in fact, introduce new concepts. See *Ex parte Grasselli*, 231 USPQ 393 (BPAI 1983).

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 16-18 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16-18 and 24 are vague and indefinite because claim 24 recites the limitation "within said SEQ ID NO: 1". Recitation of the limitation renders the claim vague and indefinite because the claim is drawn to "[a]n antibody that binds to the PST phosphatase interacting protein (PSTPIP) polypeptide of SEQ ID NO: 1" and therefore it is unclear to what other subject matter the claimed antibody might bind. The inclusion of the limitation requiring the antibody to bind the polypeptide of SEQ ID NO: 1 "within said" sequence may be merely redundant, but

since it cannot be ascertained with certainty how the limitation is meant to limit the subject matter of the claim, the claim is vague and indefinite. Accordingly, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention. Amending claim 24 to delete ", within said SEQ ID NO: 1" can obviate this ground of rejection.

Conclusion

12. No claims are allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. This application contains claims 1-14 and 19-21 drawn to an invention non-elected with traverse in Paper No. 12. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR § 1.144). See MPEP § 821.01.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Thursday, alternate Fridays, 8:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone

numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.
Examiner, Art Unit 1642

slr
August 25, 2002

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
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